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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,295	03/22/2002	Michael John Radley Young	217994US3PCT	9250

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CARTER, DELUCA, FARRELL & SCHMIDT LLP
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EXAMINER

JAWORSKI, FRANCIS J

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 02/05/2004

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,295

Applicant(s)

YOUNG ET AL.

Examiner

Jaworski Francis J.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24 - 37 are is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 24 - 37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(Parenthesized claim numerals pertain to the specific claim or claims to which the rejection portion is directed.)

Claims 24-29, 31-34, 36 - 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Oppelt et al (US5624382). Oppelt teaches method of use and structure for a plurality of tissue diathermy apparati 1,2 which heat prostatic or other subcutaneous tissue (col. 1 lines 9-12) dependent upon focal length and including (see Fig. 2 and col. 5) ultrasonic vibratory transducer means 9, plano-concave converging lens 10 for focusing the ultrasound, a fluid immersion chamber bounded by membrane 29 and enclosing the ultrasound generator and lens, and means 18-23 for moving the focal point set by the converging lens. Under one anticipatory interpretation the terminology 'being uniformly pressurized' with respect to the chamber is accorded no patentable weight since no pressurizing device is claimed; under another anticipatory interpretation the sealed chamber depicted in Fig. 2 is inherently at some uniform pressure since all seals are stated to be fluid-tight and the coupling membrane is stated to be statically pressed against the skin for focal specificity by 18-23. (Claims 24,36). Units 1 and 2 comprise a plurality of generator means 9, each having its respective

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enclosing chamber and adjacently disposed lens (Claims 25-26, 32). Alignment description in the context of the Oppelt et al face figure and col. 6 lines 16-37 is understood to state holding the transducers in such fixed confocal alignment so that the target pathology location W is heated. (Claims 27,33). The couplant chamber is filled with liquid couplant so as to be vibrationally transmissive forward of the lens and to the body surface, see col. 5 lines 42-52, and the lens is disposed adjacent to the chamber as defined by the lens face 10 – to membrane 29 portion. (Claims 28, 29, 34). Since each such lens-generator unit is movable together, movement of any of 18-23 moves the respective lens-generator pair 1 or 2; moreover col. 5 line 52 – col. 6 line 37 admits of the controller 34 acting to move both of 1 and 2 where a change in desired target confluence region W would require a change in the respective focal distances of both 1 and 2 (Claim 31). Since the prostate is a vascularized tissue, the Oppelt et al teaching also pertains to the treatment of blood vessels. (Claim 37).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-29, 31-34, 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oppelt et al (US5624382) in view of Hassler (US4957099) and Sekino et al (US5078144).

Oppelt et al is applied as above. It would have been obvious in view of Hassler which is directed to a related technology of that assignee, to modify Oppelt et al as per the face figure where the Hassler's analogous plural vibratory generators with respective adjacently disposed plano-concave lenses and focal adjustment rods 11 are commonly chambered, in order to provide a stable adjustably directable focal intersection as called for in Oppelt et al. Additionally, Hassler notes in col. 7 line 51 – 8 line 23 that when the enclosing chamber is a two-part chamber to allow inert oil to bathe the electronically active portions, the coupling chamber defined by 4, 28 (Fig. 3) may be pressurized to place the water couplant portion into tight transmissive proximity with each lens face (Claims 24-26, 32, 36). Additionally, whereas in Hassler the vibratory lithotripsy generators are designated as 'piezoelectric' it would have been obvious in view of Sekino et al col. 6 lines 6 – 21 and elsewhere that an ultrasonic piezoelectric generator such as their Fig. 28 is applicable to both tissue. Note also that focal point shift for the lens-transducer assembly may be electronic due to the frequency-dependence of Snell's Law, see col. 18 lines 13-16. (Again Claims 24-26). The relationship of the generators is fixed by joint action of rods 11 to define a common focal point, see col. 6 lines 1 – 22. (Claims 27,33). The couplant chambers immediately forward of the plano concave lens(es) defined by Hassler as well as Sekino et al act identically to that of Oppelt et al, see above and Hassler col. 5 lines 14 – 19, Sekino et al col. 3 lines 45-49 which teach direct adjacency of the transducer-lens to the couplant chamber. (Claims 28-29, 34). In addition to the applicability of Oppelt et al regarding lens-generator movement or movement of both individual lens-generator pairs 1 and 2

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where a change in targeted confluence region W so admits, in Hassler the commonly housed plurality of transducer-lens pairs are moveable together in aggregate by the main action of slide 27 and incrementing adjustment of rod 1. (Claim 31). Sekino et al teaches application to tumor tissue which is vascularized, similar to the Oppelt et al case. (Claim 37).

Claims 30, 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oppelt et al or alternatively, Oppelt et al in view of Hassler and Sekino et al as applied to claim 24 above, and further in view of Fry et al (US4858613, of record). It would have been obvious in view of the latter col. 5 lines 47-56 to form a convergent tissue heating lens of aluminum since it is an inexpensive durable material which is easy to machine into a plano-concave shape.

Response to Arguments

The content of the claimed subject matter in the newly presented claims now includes the relationship of the plano-concave lens and generator set to at least partial enclosure within a fluid chamber, and as such the rejection arguments have been modified to address same.

Since applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See

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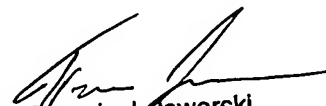
MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 703-308-3061.

FJJ:fjj

01-29-04


Francis J. Jaworski
Primary Examiner